THE REMARKS

Claims 35-39, 42, 43, and 47-49 were pending prior to entering the amendments.

The Amendments

The specification is amended to capitalize the trademarks; the generic terminologies of those trademarks were already inserted in preceding paragraphs in previous amendments dated October 29, 2008.

The amendment of Claim 35 is supported by page 20, lines 18 and 25; page 22, lines 3, and 24-25.

No new matter is introduced in any of the amendments. The Examiner is requested to enter the amendment and reconsider the application

The Response

Objection to the Specification

6. The specification is objected to because of the use of improperly demarcated trademarks. Applicants have amended the specification to correct the informalities.

Claims Objections

7. Claim 38 is objected to as allegedly being drawn in the alternative to the subject matter of non-elected species of invention.

Claim 38 is amended to delete the extra "or."

35 U.S.C. §103(a) Rejection

9. Claims 35, 38, 39, 42, 43, 48, and 49 under 35 U.S.C. §103(a) are rejected as allegedly being unpatentable over Martin et al. (*Am. J. Pathol.* 2000 May; 156 (5): 1573-1579) The rejection is overcome in view of the claim amendment.

Martin et al. evaluated 17 patients having posttransplantation lymphoproliferative disorders to determine whether $p16^{INK4a}$ expression could be correlated to morphology, EBV detection, and a Ki-67 labeling index (Abstract). To assess the proliferative status of the $p16^{INK4a}$

positive cells, double labeling with anti-p16 and anti-Ki67 were performed (page 1574, right column). At page 1576, the end of right column, Martin et al. reported that most of the $p16^{INK4a}$-positive cells were ki-67 negative, except for patient 12, who had numerous double-labelled cells.

Claim 35, as amended, is directed to a research or diagnostic kit for detecting cervical dysplasia or neoplasma. In order to detect cervical dysplasia or neoplasma, a positive control of cervical cells immunoreactive for $p16^{INK4a}$ and Ki67 is included in the kit. The present application has demonstrated that in dysplasia specimen from uterine cervix, many cells were doubly stained by both $p16^{INK4a}$ antibody and Ki67 antibody; whereas in metaplasia specimen from uterine cervix, there were no cells doubly stained by both $p16^{INK4a}$ antibody and Ki67 antibody (Examples 1, 6, and 7).

Because Martin et al. do not teach or suggest a method of differentiating cervical dysplasia or cervical neoplasma from metaplasia, it would not have been obvious to include a positive control of cervical cells immunoreactive for $p16^{INK4a}$ and Ki67 in a kit, based on the teaching of Martin et al.

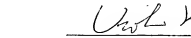
Therefore, the 103(a) rejection of Claims 35, 38, 39, 42, 43, 48, and 49 should be withdrawn.

Rejoinder

Once the Examiner finds the elected species allowable, Applicants request that the Examiner rejoin Claims 36, 37, and 47, which are dependent claims of Claim 35.

Date: March 18, 2009

Respectfully submitted,



Viola T. Kung, Ph.D. (Reg. No. 41,131)

HOWREY LLP
2941 Fairview Park Drive, Box 7
Falls Church, VA 22042
Tel: (650) 798-3570
Fax: (650) 798-3600